REMARKS

Claims 1, 8-9, and 14 have been rejected under Section 102 based on United States Patent Number 5,397,312 (Rademaker et al.). Claims 3, 10 and 15 have been rejected under Section 102 based on United States Patent Number US 5,158,535 (Paul et al.). Claims 5, 6 and 11 have been rejected under Section 103 based on Rademaker et al. Claims 2, 4 and 7 have been rejected under Section 103 based Rademaker et al. in view of United States Patent Number 5,314,464 (KenKnight et al). The pending office, dated 22 February 2005, has been carefully considered and reconsideration of the application is respectfully requested.

Independent claims 1 and 3 have been amended to make changes of an editorial nature, and to limit the invention to features which clearly distinguish the claimed invention over the cited prior art. Independent claim 2 and dependent claim 8 have been amended to make changes of an editorial nature, and to more clearly to define the invention.

In claims 1 and 3, as amended, the device is limited to having a straight barrel with the portion of the passage located in the barrel, being linear. Furthermore, the gripping portion has also been introduced into the tampon insertion device of claim 3, to correspond with claim 1. In the claims, the term "non-flowable object or non-flowable medicament" has been replaced by the term "solid object or medicament" in order more clearly to define the claimed invention. All of the amendments draw clear support from the specification as filed, e.g. page 3, lines 20-24 and page 9, lines 23 and 28. The amendments to the claims overcome the basis for the rejections under Sections 102 and 103, as discussed below.

Claims 1, 8, 9 and 14 stand rejected under 35 USC 102(b) as being anticipated by Rademaker et al., which discloses an applicator for introducing a cream-type substance into a woman's vagina. (Rademaker, Abstract) The applicator includes a holder (a barrel) which is externally slightly curved. The applicator also has a handle which is slightly curved. The holder or barrel is oval-shaped in cross-sectional outline.

Claim 1, as amended, requires the device of the invention to be a device for use by a female user to self-deposit a solid object or solid medicament in her vagina, the device having a straight barrel extending from a gripping portion with a portion of a passage, extending through the barrel, being linear. The device of Rademaker et al. is an applicator for introducing a cream-type substance (not a solid object or a solid medicament), has a curved

barrel extending from its gripping portion, and the portion of its passage extending through the barrel is also curved. Rademaker et al. does not teach or suggest a linear barrel extending from a gripping portion with a portion of the passage, located in the gripping portion, being curved in the longitudinal direction of the passage and a portion of the passage, located in the barrel, being linear. Instead, Rademaker et al. specifically teaches away from a linear barrel (Rademaker, column 1, lines 33-45). The Applicant thus respectfully submits that claim 1, as amended, is clearly distinguishable over the disclosure of Rademaker et al.

Claim 8 requires the passage of the device of the invention to include a medicament or object chamber for receiving a solid medicament or solid object. In contrast, Rademaker et al. discloses a space 4 for accommodation of a cream. (Rademaker, Figure 2 & column 2, line 62 - column 3, line 5).

Claim 9 requires the chamber to be spaced from the outlet of the passage so that a part of the barrel, above the outlet, and a part of the barrel, below the outlet, can be displaced or forced towards each other when the barrel is being inserted into a vagina to close the outlet thereby to prevent an object or medicament inside the chamber from scraping against or injuring body tissue material. These lip-like features are also not disclosed by Rademaker et al. The applicator of Rademaker et al. merely has a round opening 3 with two opposite, lateral cavities 5 designed to allow air to escape from the space 4 when the cream is being introduced from a tube into the space 4 and the tube is projecting with its tip fitting in the passage opening 3 (Rademaker, column 2, line 68 - column 3, line 5). Rademaker et al. thus does not teach the "lips" of claim 9. This is not surprising, as the applicator of Rademaker et al. is intended to introduce a cream-type substance into a woman's vagina and not a solid, hard object. There is thus no need for the outlet 3 of the applicator of Rademaker et al. to squeeze shut during insertion into a vagina in order to protect body tissue material. Furthermore, Rademaker et al. teaches that the holder (i.e. the barrel) will typically be of polycarbonate or polystyrene (Rademaker, column 5, lines 1-5), which will render the holder stiff. It is thus unlikely that part of a polycarbonate or polystyrene barrel, above the outlet, and a part of such a barrel, below the outlet, will be displaceable in a lip-like manner, which is in effect what is required by claim 9.

Claims 3, 10 and 15 stand rejected under 35 USC 102(b) as being anticipated by Paul et al. , which discloses a curved tampon applicator comprising first and second arcuately shaped

tubular members telescopically joined together. One of the members thus defines a barrel and a gripping portion (a finger-grip portion). The other of the curved members defines an ejector or plunger which in use is displaced along a curved passage defined through the barrel to push a tampon out of the passage.

Claim 3, as amended, requires the barrel to be straight and a portion of the passage, located in the barrel, to be linear. A portion of the passage, in the gripping portion, must be curved in the longitudinal direction of the passage. Although Paul et al. does disclose that a portion of the passage, located in the gripping portion, is curved, Paul et al. does not disclose the combination of such a gripping portion with an elongate straight barrel defining a linear passage. In fact, Paul et al. teaches away from such a tampon insertion device (see column 2, lines 64-68). Paul et al. thus do not teach all the features of the tampon insertion device as claimed in amended claim 3.

Regarding claim 10, the Examiner states that Paul et al. discloses that the barrel 14 has a longitudinally extending slit (at end 46) through which a string 13 of a tampon 12 received in the passage can protrude. Claim 10 requires the barrel to include a longitudinally extending slit through which a string of a tampon received in the passage can protrude. The tampon applicator of Paul et al. clearly does not have a longitudinally extending slit in the barrel 14. Instead, an outlet is merely provided in the plunger 16 (at end 46). The outlet at end 46 is not a longitudinally extending slit, and it is also not a longitudinally extending slit in the barrel 14, as required by claim 10. Accordingly, the features of claim 10 are also neither taught nor suggested by Paul et al.

Claim 15 requires a part of the barrel, above the outlet, and a part of the barrel, below the outlet, to be displaceable towards each other when the barrel is being inserted into a vagina, thus at least partially closing off the outlet. Contrary to statements the office action, this feature is not taught by Paul et al. . Rather, Paul et al. teaches a conventional petal outlet. The petals are thin, flexible members separated by slots or grooves and are capable of bending radially outward as the tampon is expelled from the curved tampon applicator. When being inserted into a vagina, the petals are in a closed position and lie against the point of the tampon. Inward displacement of the petals is prohibited by the presence of the tampon and the configuration of the petals. The petals of the applicator of Paul et al. are intended to prevent the outer tube from collapsing or flattening (Paul, column 4, lines 11-15) after the

tampon has been expelled. When the tampon is still present in the outer tube, the outer tube will thus definitely also not collapse or flatten and the petals will not move any closer together than they already are. In contrast, the "lips" of the barrel of the device of the present invention are intended to allow the barrel to collapse or flatten or squeeze shut when the barrel is being inserted into a vagina, thereby to close off the outlet whilst the barrel is being inserted.

Claims 5, 6 and 11 stand rejected under 35 USC 103(a) as being unpatentable over Rademaker et al. Assuming *arguendo* that Rademaker's curved structure has a longitudinal axis at all, and that Rademaker et al. does disclose that a centrally disposed longitudinal axis of the barrel and a centrally disposed axis through the inlet of the passage are at an obtuse angle, Rademaker et al. does not disclose that the angle should be between 170 ° and 135°, as the Examiner noted. The Examiner argues that an angle within this range would have been obvious to one of ordinary skill in the art, because Rademaker et al. teaches that the applicator should be curved so that it follows the natural curvature of the vagina. The obtuse angle of between 170 ° and 135 ° claimed in claim 5 was, however, not selected by the inventor as a result of any alleged curvature of the vagina, but because of the angle of inclination of the vagina of a standing woman relative to the horizontal. The inventor, a gynecologist by profession, is in fact of the view that the vagina is not curved at all and is substantially linear or straight. Rademaker et al. makes no reference to this angle of inclination and Rademaker et al. therefore also does not teach that the obtuse angle should be between 170 ° and 135 °, nor does Rademaker et al. suggest such an obtuse angle or indicate any link between a suitable obtuse angle and the angle of inclination of the vagina. The claimed angle of between 170° and 135° of claim 5, and the angle of between 160 ° and 140 ° of claim 6, can thus not be obvious in the light of Rademaker et al.

In regard to claim 11, although Rademaker et al. teaches that the barrel is to be made from synthetic plastics or polymeric materials, Rademaker et al. refers to polycarbonate or polystyrene as suitable examples. Rademaker et al. appears to prefer a stiff holder, although they do mention that, when the piston is not flexible, the holder must be flexible. In either event, however, the applicator will be rigid. The flexibility that is implied when a material with a Shore A hardness of between 40 and 80 is selected, is thus neither taught nor suggested by Rademaker et al. The flexibility implied by the selection of a material having a

Shore A hardness of between 40 and 80, may provide and advantage for clinical reasons. A flexible barrel will reduce pain and trauma and promote ease of insertion. These advantages are not mentioned or considered by Rademaker et al; instead, Rademaker et al. teaches that the holder be of a material that is transparent, impact-resistant, heat-resistant, suitable for pharmaceutical application, and recyclable or destructible, with a surface which can be made smooth and polish-finished and which preferably be such that it can be colored. Applicant's reference to advantages relate only to claim 11, and the limitation relating to hardness should not be read into other claims.

Claims 2, 4 and 7 stand rejected under 35 USC 103(a) as being unpatentable over Rademaker et al. in view of KenKnight et al. The Applicant respectfully submits that the office action does not establish a prima facie case of obviousness. KenKnight et al. discloses a tool and method for inserting cardiac defibrillation electrodes into a patient. The tool of KenKnight et al. is for use by one person on another person. In contrast, the device of the present invention is for use by a woman to insert an object into her vagina without the assistance of any other person. The tool of KenKnight et al. is for invasive clinical use, whereas the applicator of the present invention is not invasive. These devices are therefore clinically not comparable and are not analogous art. Moreover, the Examiner has provided no objective reasons why a person skilled in the art, faced with the problem of how to improve a device for use by a female user to self-deposit a solid object or a solid medicament into her vagina, would turn to KenKnight et al., which relates to a tool for inserting cardiac defibrillation electrodes into a patient, for inspiration. There is no suggestion or motivation or expression of desirability in either Rademaker et al. or KenKnight et al. to modify these references or to combine reference teachings, and these references can not be viewed with the impermissible hindsight or the suggestion afforded by the present invention. Not only is there no incentive to combine, but a person skilled in the art considering the teachings of KenKnight et al. would not have a reasonable expectation of success in applying the teachings of KenKnight et al. to a device for use to introduce a solid object or solid medicament into a vagina. And there has been no indication that such a person would have a reasonable expectation of success.

Furthermore, the Examiner is incorrect in stating that the barrel 26 of KenKnight et al. has a penile-shaped or roughly triangular cross-section. The applicator tool 10 of KenKnight

et al. includes an outer electrode support tube 12 beginning at a proximal end 14 and terminating at a rounded distal end 16. A slidable sleeve 24 circumferentially surrounds the support tube 12. An actuating rod 26 extends through the support tube 12 and a conically shaped distal tip 30 is securely connected to a distal end 28 of the actuating rod 26. The support tube 12 is cylindrical (or oval) and not penile-shaped or roughly triangular in cross-section. This is clear from a number of passages in the specification of KenKnight et al., e.g. column 2, lines 51-53, column 3, line 49, column 3, lines 62-65 and column 4, lines 12-17. Thus, neither is the barrel (support tube 12) of KenKnight et al. penile-shaped or roughly triangular in cross-section, as required by claims 2 and 4, nor does the distal tip 30 define an outlet end portion of the barrel (it is attached to the actuation rod 26). Furthermore, the distal tip 30 is conically shaped and does not have the general shape of a glans penis, as required by claim 7.

Rademaker et al., and Paul et al. , in combination, do not disclose all of the features of claim 13, which depends from claim 1. Such a combination does not teach a device having an elongate straight barrel nor gripping surfaces arranged such that, when the body is being held between a thumb, an index finger and a middle finger of one hand of a user, with both the middle finger and the index finger touching the body in respective areas and the body being orientated such that said areas are in the same horizontal plane, the barrel projects upwardly away from said horizontal plane at an angle of between 45 ° and 10 °. Paul et al. merely discloses ribs 34 circumferentially arranged around the finger grip portion 20. When the finger grip 20 is held between a thumb, an index finger and a middle finger of one hand of a user, with the middle finger and the index finger touching the gripping portion in respective areas and the gripping portion is arranged such that said areas are on the same horizontal plane (typically below the gripping portion 20), the barrel 14 will not project upwardly away from the horizontal plane at an angle of between 45 ° and 10 °, but will project away from the horizontal plane at an increasing angle starting at about 0 ° and ending at about 10 °. The device of the invention, as claimed in claim 15, is designed so that when the gripping portion or handle is held with the hand in a relaxed natural position, the barrel or shaft will automatically be aligned with the axis of the vagina along the plane of vaginal inclination. The gripping surfaces therefore serve a specific and very important function of directional control and alignment of the barrel and are not merely gripping surfaces as taught by Paul et

al. for holding the applicator.

Conclusion

In view of the above, all claims presently of record are believed to be patentably distinguishable from the cited art. Thus, all rejections of record are believed to have been overcome and the application is believed to be in allowable form. An early Notice of Allowability is earnestly solicited and is believed to be fully warranted.

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